

Appl. No. 10/015,220  
RCE and Amdt. dated April 23, 2004  
Reply to Final Office Action of Nov. 21, 2003  
Docket No. RADNT-031A

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claim 1 (Canceled) A heat exchange/intra-aortic counterpulsation catheter device comprising:  
an elongate catheter having a proximal end and a distal end, said catheter being advancable,  
distal-end-first, into the aorta of a human or veterinary patient;  
a counterpulsation balloon useable for effecting intra-aortic balloon counterpulsation; and,  
a heat exchanger useable to cool at least a portion of the patient's body to a temperature that  
is at least 1 °C below normothermia.

Claim 2 (Canceled) A device according to Claim 1 wherein the heat exchanger comprises a heat  
exchanger through which heat exchange fluid is circulated.

Claim 3 (Canceled) A device according to Claim 2 wherein said heat exchanger comprises a heat  
exchange balloon.

Claim 4 (Canceled) A device according to Claim 3 wherein the heat exchanger comprises a single-  
lobed heat exchange balloon.

Claim 5 (Canceled) A device according to Claim 3 wherein the heat exchanger comprises a multi-  
lobed heat exchange balloon.

Claim 6 (Canceled) A device according to Claim 1 wherein at least a portion of the heat exchanger  
is metallic.

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Claim 7 (Canceled) A device according to Claim 3 wherein the heat exchange balloon and the counterpulsation balloon comprise a single balloon that is useable for both counterpulsation and heat exchange.

Claim 8 (Canceled) A device according to Claim 1 wherein the heat exchanger comprises a heat exchange surface and wherein the device further comprises a flow disruption surface associated with the heat exchange surface, the flow disruption surface being configured to disrupt the laminarity of blood flow adjacent to the heat exchange surface, thereby enhancing the efficiency by which the heat exchanger exchanges heat with the flowing blood.

Claim 9 (Canceled) A device according to Claim 1 wherein the counterpulsation balloon is positioned at a first location on the catheter and the heat exchanger comprises a heat exchange surface located at a second location on the catheter .

Claim 10 (Canceled) A device according to Claim 9 wherein the first location is closer to the distal end of the catheter than the second location.

Claim 11 (Canceled) A device according to Claim 9 wherein the second location is closer to the distal end of the catheter than the first location.

Claim 12 (Canceled) A device according to Claim 9 wherein the heat exchanger and the counterpulsation balloon comprise a single balloon which is a) configured and useable to effect intraaortic counterpulsation and b) receives a heat exchange medium such that heat is exchanged between the heat exchange medium and the blood, through at least a portion of the balloon.

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Claim 13 (Canceled) A system comprising a heat exchange/intraortic counterpulsation catheter device according to Claim 1, further in combination with:

apparatus attachable to the catheter and useable to cause a) inflation and deflation of the counterpulsation balloon in response to the patient's cardiac cycle to effect intra-aortic balloon counterpulsation that results in a beneficial effect on the patient and b) at least cooling (and preferable cooling or heating) of the heat exchanger to cause cooling of at least a portion of the patient's body (e.g., the heart) to a temperature that is at least 1 °C below normothermia.

Claim 14 (Canceled) A method for treating a human or veterinary patient who suffers from congestive heart failure or another condition wherein the patients cardiac output is subnormal, said method comprising the steps of:

- a. providing a heat exchange/intraortic counterpulsation catheter comprising i) an elongate catheter having a proximal end and a distal end, said catheter being advancable, distal-end-first, into the aorta of the patient, ii) a counterpulsation balloon useable for effecting intra-aortic balloon counterpulsation; and, a heat exchanger useable to cool at least a portion of the patient's body to a temperature that is at least 1 °C below normothermia.
- b. advancing the heat exchange/intraortic counterpulsation catheter, distal end first, into the patient's aorta such that the counterpulsation balloon is positioned in the thoracic aorta;
- c. driving and controlling the counterpulsation balloon and heat exchanger so as to effect intra-aortic balloon counterpulsation while cooling and/or maintaining the temperature of at least a portion of the patient's body to a temperature that is at least 1 °C below normothermia.

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Claim 15 (Canceled) A method according to Claim 14 further comprising the step of:

- d. administering an antishivering treatment to the patient.

Claim 16 (Canceled) A method according to Claim 14, wherein the patient's body temperature is cooled to and maintained within the range of 32-34°C while intraaortic counterpulsation is performed.

Claim 17 (Canceled) A method according to Claim 15 wherein the anti-shivering treatment is selected from the group of anti-shivering treatments consisting of: i) administering a therapeutically effective amount of an anti-shivering agent to the donor; ii) applying warmth to the skin of the donor and iii) administering a therapeutically effective amount of an anti-shivering agent to the donor and applying warmth to the skin of the donor.

Claim 18 (Canceled) A method according to Claim 15 wherein the anti-shivering treatment comprises administering to the donor a therapeutically effective amount of at least one anti-shivering agent selected from the group consisting of: i) dopamine receptor antagonists; ii) dopamine receptor agonists; iii)  $\kappa$ -opioid receptor agonists; iv) opioid agonist-antagonist analgesics and serotonin 5HT<sub>1a</sub> receptor agonists.

Claim 19 (Currently amended) A method for treating a human or veterinary patient who suffers from a condition wherein the patient's cardiac output is subnormal, said method comprising the steps of:

- a. providing a heat exchange catheter system comprising i) a heat exchange catheter body, ii) at least one heat exchanger for exchanging heat with blood flowing through a blood vessel into which the heat exchange catheter body is inserted, iii) a

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temperature sensor for sensing the temperature of at least a portion of the patient's body and iv) a controller adapted to receive an indication of the sensed patient temperature from the temperature sensor and to control the heat exchanger in response to said sensed patient temperature such that the heat exchanger will cool at least a portion of the patient's body to a target temperature that is at least 1 °C below normothermia;

- b. providing an intra-aortic balloon counterpulsation catheter comprising i) a counterpulsation catheter body and ii) a counterpulsation balloon useable for effecting intra-aortic balloon counterpulsation;
- c. inserting the heat exchange catheter into the patient's venous vasculature such that blood flows in heat exchange proximity to the heat exchanger;
- d. inserting the intra-aortic balloon counterpulsation catheter into the patient's vasculature such that the counterpulsation balloon is positioned within the patient's aorta;
- e. using the intra-aortic balloon counterpulsation catheter to effect intra-aortic balloon counterpulsation while the heat exchange catheter system cools the temperature of [at least a portion of] the patient's [body] heart to a temperature that is at least 1 °C below normothermia; and
- f. controlling said heat exchange catheter to maintain said cooling of the patient's heart to cause an increase in cardiac output and a decrease in cardiac metabolic demand.

Claim 20 (Currently amended) A method according to Claim 19 further comprising the step of:

- [[f]] g. administering an antishivering treatment [to the patient] to the patient.

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Claim 21 (Original) A method according to Claim 20 wherein the wherein the anti-shivering treatment is selected from the group of anti-shivering treatments consisting of: i) administering a therapeutically effective amount of an anti-shivering agent to the donor; ii) applying warmth to the skin of the donor and iii) administering a therapeutically effective amount of an anti-shivering agent to the donor and applying warmth to the skin of the donor.

Claim 22 (Original) A method according to Claim 20 wherein the anti-shivering treatment comprises administering to the donor a therapeutically effective amount of at least one anti-shivering agent selected from the group consisting of: i) dopamine receptor antagonists; ii) dopamine receptor agonists; iii)  $\kappa$ -opioid receptor agonists; iv) opioid agonist-antagonist analgesics, v) serotonin 5HT<sub>1a</sub> receptor agonists and vi) alpha-2 adrenergic receptor agonists.

Claim 23 (Original) A method according to Claim 19, wherein the patient's body temperature is cooled to and maintained within the range of 32-34°C while intra-aortic counterpulsation is performed.

Claim 24 (Canceled) A method according to Claim 19 wherein the heat exchanger is positioned in a vein.

Claim 25 (Currently amended) A method according to Claim ~~[[24]]~~ 19 wherein the heat exchanger is positioned in the vena cava.

Claim 26 (Withdrawn) A method according to Claim 19 wherein the heat exchange catheter provided in Step A and the intra-aortic balloon counterpulsation catheter provided in Step B comprise a single catheter body having both a heat exchanger and a counterpulsation balloon

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thereon.

Claim 27 (Previously presented) A method according to Claim 19 wherein the heat exchange catheter provided in Step A and the intra-aortic balloon counterpulsation catheter provided in Step B comprise separate catheters.